

Introduced by Senator Ortiz

December 6, 2004

An act to add Division 113 (commencing with Section 130600) to the Health and Safety Code, relating to prescription drugs, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

SB 19, as introduced, Ortiz. California Rx Program.

Under existing law, the State Department of Health Services administers the Medi-Cal program, and is authorized, among other things, to enter in to contracts with certain drug manufacturers. Under existing law, the department is entitled to drug rebates in accordance with certain conditions, and drug manufactures are required to calculate and pay interest on late or unpaid rebates.

This bill would establish the California Rx Program, to be administered by the department. The bill would authorize the department to negotiate drug rebate agreements with drug manufacturers to provide for program drug discounts. The bill would authorize any licensed pharmacy or drug manufacturer to provide services under the program. The bill would establish eligibility criteria and application procedures for California residents to participate in the program.

The bill would establish the California Rx Program Fund, as a continuously appropriated fund, into which all payments directly received under the program would be deposited.

The bill would appropriate \$3,000,000 from the State Treasury to the department to fund staff and contract costs for the program.

The Pharmacy Law is administered by the California State Board of Pharmacy in the Department of Consumer Affairs.

This bill would require the Department of Consumer Affairs to implement, as a part of the California Rx Program that would be established under the bill, a Prescription Drug Resource Center Web site to educate California consumers about options for lowering prescription drug costs.

Vote: $\frac{2}{3}$. Appropriation: yes. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Division 113 (commencing with Section 130600) is added to the Health and Safety Code, to read:

DIVISION 113. CALIFORNIA RX PROGRAM

CHAPTER 1. GENERAL PROVISIONS

130600. (a) This division shall be known, and may be cited, as the California Rx Program.

(b) For the purposes of this division, the following definitions shall apply:

(1) "Department" means the State Department of Health Services.

(2) "Fund" means the California Rx Program Fund.

(3) "Prescription drug" means any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

(4) "Private discount drug program" means a prescription drug discount card or manufacturer patient assistance program that provides discounted or free drugs to eligible individuals. For purposes of this division, a private discount drug program is not considered an insurance or a third-party payer program.

(5) "Program" means the California Rx Program.

(6) "Recipient" means a resident that has completed an application and has been determined to be eligible for the program.

(7) "Resident" means a California resident pursuant to Section 17014 of the Revenue and Taxation Code.

130602. (a) There is hereby established the California Rx Program.

1 (b) Any California resident may enroll in the program if
2 determined eligible pursuant to Section 130605.

3
4 CHAPTER 2. ELIGIBILITY AND APPLICATION
5 PROCEDURES
6

7 130605. (a) To be eligible for the program, an individual
8 shall meet all of the following requirements at the time of
9 application and reapplication for the program:

10 (1) Be a resident.

11 (2) Have family income, as reported pursuant to Section
12 130606, that does not exceed 400 percent of the federal poverty
13 guidelines, as revised annually by the United States Department
14 of Health and Human Services in accordance with Section 673(2)
15 of the Omnibus Budget Reconciliation Act of 1981 (42 U.S.C.
16 Sec. 9902), as amended, or be a resident whose family incurs
17 unreimbursed expenses for prescription drugs equal to or greater
18 than 5 percent of family income, or be a resident whose family
19 incurs unreimbursed medical expenses equal to or greater than 15
20 percent of family income.

21 (3) Not have or be eligible for outpatient prescription drug
22 coverage paid for in whole or in part by any of the following:

23 (A) The Medi-Cal program.

24 (B) The children's health insurance program.

25 (C) Another health plan or pharmacy assistance program that
26 uses state or federal funds to pay part or all of the cost of the
27 individual's outpatient prescription drugs. Notwithstanding any
28 other provision of this division to the contrary, an individual
29 enrolled in Medicare may participate in this program, to the
30 extent allowed by federal law, for prescription drugs not covered
31 by Medicare.

32 (b) Application and a simple annual reapplication for the
33 program shall be made pursuant to subdivision (d) of Section
34 130606. An applicant may apply or reapply on behalf of the
35 applicant and the applicant's spouse and children. The guardian
36 or custodian of an applicant may apply or reapply on behalf of
37 the applicant.

38 130606. (a) The department shall develop an application
39 form for the determination of a resident's eligibility for the
40 program.

1 (b) The application, at a minimum, shall do all of the
2 following:

3 (1) Specify the information that an applicant or the applicant's
4 representative must include in the application about the applicant.

5 (2) Require that the applicant attest that the information the
6 applicant provides in the application is accurate to the best
7 knowledge and belief of the applicant.

8 (3) Specify that the application fee is due upon application
9 submission. The application fee shall be ten dollars (\$10) for the
10 initial enrollment. The initial application may be made at
11 participating pharmacies or through a private third-party vendor.

12 (c) In assessing the income requirement for program
13 eligibility, the department shall use the income information
14 reported on the application and not require additional
15 documentation.

16 (d) Application and annual reapplication may be made at any
17 pharmacy participating in the program. The pharmacy
18 completing the application shall keep the application fee as
19 reimbursement for its cost of processing the application. If it is
20 determined the applicant is already enrolled in the program, the
21 pharmacy shall return the fee to the applicant and inform the
22 applicant of his or her current status as a recipient.

23 (e) The department may provide for a secure electronic
24 application process that can be used by pharmacies to enroll
25 applicants in the program.

26 (f) During normal hours, the department shall make a
27 determination of eligibility within four hours of receipt of the
28 application. The department shall mail the recipient an
29 identification card no later than four days after eligibility has
30 been determined.

31 (g) For applications submitted through a pharmacy, the
32 department may issue a recipient identification number for
33 eligible applicants to the pharmacy for immediate access to the
34 program.

35 130607. (a) The department shall execute agreements with
36 private discount drug programs to provide a simple point of entry
37 for eligibility determination and claims processing for drugs
38 available in those private discount drug programs.

1 (b) (1) An applicant may be required to provide additional
2 information to determine the applicant's eligibility for other
3 discount card and patient assistance programs.

4 (2) An applicant shall not be, under any circumstances,
5 required to participate in, or to disclose information that would
6 determine the applicant's eligibility to participate in, these
7 private discount drug programs in order to participate in the
8 program provided for in this division.

9 (c) For those drugs available pursuant to subdivision (a), the
10 department shall develop a system that provides a recipient with
11 the best prescription drug discounts that are available to them
12 through the program or through private discount drug programs.

13 (d) The recipient identification card issued pursuant to
14 subdivision (f) of Section 130606 shall serve as a single point of
15 entry for drugs available pursuant to subdivision (a) and shall
16 meet all legal requirements for a health benefit card.

17
18 CHAPTER 3. ADMINISTRATION AND SCOPE
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20 130615. The department shall conduct outreach programs to
21 inform residents about this program. No outreach material shall
22 contain the name or likeness of a drug or the likeness of an
23 elected state official.

24 130616. (a) Any pharmacy licensed pursuant to Chapter 9
25 (commencing with Section 4000) of Division 2 of the Business
26 and Professions Code may participate in the program provided
27 for under this division.

28 (b) Any drug manufacturer may participate in the program
29 provided for under this division.

30 130617. (a) The amount a recipient pays for a drug within the
31 program shall be equal to the participating provider's usual and
32 customary charge or the pharmacy contract rate pursuant to
33 subdivision (c), less a program discount for the specific drug or
34 an average discount for a group of drugs or all drugs covered by
35 the program.

36 (b) In determining program discounts on individual drugs, the
37 department shall take into account the rebates provided by the
38 drug's manufacturer and the state's share of the discount.

1 (c) The department may contract with participating
2 pharmacies for a rate other than the pharmacies' usual and
3 customary rate.

4 (d) The department shall provide a claims processing system
5 that complies with all of the following requirements:

6 (1) Provides for the price that meets the requirements of
7 subdivision (b).

8 (2) Provides the pharmacy with the dollar amount of the
9 discount to be returned to the pharmacy.

10 (3) Provides a single point of entry for access to private
11 discount drug programs pursuant to Section 130607.

12 (4) Provides drug utilization review warnings to pharmacies
13 consistent with the drug utilization review standards outlined in
14 Section 1927 of the federal Social Security Act (42 U.S.C. Sec.
15 1396r-8(g)).

16 (e) The department shall pay a participating pharmacy the
17 discount provided to recipients pursuant to subdivision (b) by a
18 date that is not later than two weeks after the claim is received by
19 the department.

20 130618. (a) The department shall negotiate drug rebate
21 agreements with drug manufacturers to provide for program drug
22 discounts.

23 (b) The drug rebate agreements shall do all of the following:

24 (1) Specify which of the manufacturer's drugs are included in
25 the agreement.

26 (2) Permit the department to remove a drug from the
27 agreement in the event of a dispute over the drug's utilization.

28 (3) Require the manufacturer to make a rebate payment to the
29 department for each drug specified under paragraph (1)
30 dispensed to a recipient.

31 (4) Require the rebate payment for a drug to be equal to the
32 amount determined by multiplying the applicable per unit rebate
33 by the number of units dispensed.

34 (5) Define a unit, for purposes of the agreement, in compliance
35 with the standards set by the National Council of Prescription
36 Drug Programs.

37 (6) Require the manufacturer to make the rebate payments to
38 the department on at least a quarterly basis.

39 (7) Require the manufacturer to provide, upon the request of
40 the department, documentation that the department can use to

1 validate that the per unit rebate provided complies with
2 paragraph (4).

3 (8) Permit a drug manufacturer to audit claims for the drugs
4 the manufacturer provides under the program. Claims
5 information made available to a manufacturer pursuant to this
6 paragraph shall comply with all federal and state privacy statutes
7 to protect a recipient's individual health information.

8 (9) Develop a program to prevent the occurrence of fraud in
9 the program.

10 (10) Develop a mechanism for recipients to report problems or
11 complaints regarding the program.

12 (c) If the department receives a determination that the
13 California Rx Program is a state pharmaceutical assistance
14 program for purposes of federal law pursuant to Section 130621,
15 the department shall seek to contract for drug rebates that result
16 in a net price equal to the lowest price paid for the drug by the
17 federal government.

18 (d) To obtain the most favorable discounts, the department
19 may limit the number of drugs available within the program,
20 including through development of a formulary or preferred drug
21 list.

22 (e) No less than 95 percent of the drug rebates negotiated
23 pursuant to this section shall go to reducing the cost to
24 participants in the program of purchasing drugs. The Legislature
25 shall annually appropriate an amount to cover the state's share of
26 the discount provided by this section.

27 (f) The department may collect prospective rebates from drug
28 manufacturers for payment to pharmacies pursuant to subdivision
29 (e) of Section 130617. The amount of the prospective rebate shall
30 be contained in drug rebate agreements executed pursuant to this
31 section.

32 (g) The names of manufacturers and labelers who do and do
33 not enter into rebate agreements pursuant to this division are
34 public information. The department shall release the information
35 to health care providers and the public. The department may
36 impose prior authorization requirements in the Medi-Cal
37 program, as permitted by law, on the drugs of any manufacturer
38 or labeler that either does not agree to provide rebates pursuant to
39 this section or does not agree to provide rebates that result in
40 drug prices that are equal to the lowest price paid for its drugs by

1 the federal government. A prior authorization requirement
2 imposed pursuant to this subdivision shall be consistent with the
3 goals of the California Rx Program and the requirements of Title
4 XIX of the federal Social Security Act (42 U.S.C. Sec. 1396 et
5 seq).

6 130619. (a) The department shall deposit all payments the
7 department directly receives pursuant to Section 130618 and any
8 other provision of this division into the California Rx Program
9 Fund, which is hereby established in the State Treasury.

10 (b) Notwithstanding Section 13340 of the Government Code,
11 the fund is hereby appropriated to the department without regard
12 to fiscal years for the purpose of providing payment to
13 participating pharmacies pursuant to Section 130617 and for
14 defraying the costs of administering this division.
15 Notwithstanding any other law, no money in the fund is available
16 for expenditure for any other purpose or for loaning or
17 transferring to any other fund, including the General Fund.

18 130620. (a) The department may hire any staff needed for the
19 implementation and oversight of the program established under
20 this division.

21 (b) The department may contract with one or more public or
22 private entities, such as pharmacy benefit management
23 companies, to implement or administer the program completely
24 or in part.

25 (c) (1) Drug rebate contracts negotiated by a third-party
26 vendor shall be subject to review by the department.

27 (2) The department shall not enter into a contract, and may
28 cancel a contract, negotiated by a third-party vendor pursuant to
29 paragraph (1) that it finds not to be in the best interest of the state
30 or the recipients of the program.

31 (3) The third-party vendor may directly collect rebates from
32 manufacturers in order to facilitate payment to pharmacies
33 pursuant to subdivision (f) of Section 136017.

34 (4) The department shall develop a system to prevent
35 diversion of funds collected by the third-party vendor.

36 (d) Any entity with whom the department is contracting
37 pursuant to subdivision (b) shall issue a monthly report to the
38 department that, at a minimum, provides all of the following:

39 (1) Drug utilization information.

40 (2) Amounts paid to pharmacies.

1 (3) Amounts of rebates collected from manufacturers.

2 (4) The information provided in paragraphs (1), (2), and (3), at
3 the national drug code level.

4 (5) A summary of the problems or complaints reported
5 regarding the program.

6 (e) Payment of fees to entities contracting pursuant to
7 subdivision (b) shall be from the fund.

8 (f) (1) The department shall require any pharmacy benefits
9 manager that it contracts with to pass on to the department any
10 revenues, rebates, or discounts that it receives from
11 pharmaceutical manufacturers and labelers or other entities in
12 connection with prescription drug benefits specific to the
13 program.

14 (2) The department shall prohibit the disclosure or sale of
15 enrollee utilization data by the pharmacy benefits manager to any
16 person or entity other than the department.

17 130621. The department shall seek and obtain confirmation
18 from the federal Centers for Medicare and Medicaid that the
19 program established pursuant to this division complies with the
20 requirements for a state pharmaceutical assistance program
21 pursuant to Section 1927 of the federal Social Security Act (42
22 U.S.C. Sec. 1396r-8) and that discounts provided under the
23 program are exempt from the Medicaid best price.

24 130622. Notwithstanding Chapter 3.5 (commencing with
25 Section 11340) of Part 1 of Division 3 of the Government Code,
26 the director may implement this article, in whole or in part, by
27 means of a provider bulletin, or other similar instructions,
28 without taking regulatory action.

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31 CHAPTER 4. PRESCRIPTION DRUG RESOURCE CENTER
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33 130630. (a) The Department of Consumer Affairs shall
34 implement a Prescription Drug Resource Center Web site to
35 educate California consumers about options for lowering their
36 prescription drug costs.

37 (b) The Web site shall include information about public and
38 private drug coverage and drug discount programs that are
39 available to California seniors and other consumers and tips for

1 cutting costs on medications, including guidance concerning
2 generic drugs.

3 (c) (1) The Web site shall also include information about
4 ordering prescription drugs from Canada and other countries.

5 (2) Subject to paragraph (3), this information shall include a
6 list of pharmacies that the California State Board of Pharmacy
7 has determined meet pharmacy management practices required of
8 pharmacies licensed to operate in California and United States
9 and a list of medications that can be ordered through the Web site
10 from licensed pharmacies in Canada and other countries.

11 (3) For purposes of paragraph (2), the department may either
12 provide a direct link for consumers to pharmacies in Canada and
13 other countries or provide a link for consumers to other Web sites
14 if the California State Board of Pharmacy determines that the
15 pharmacies listed in those other Web sites meet pharmacy
16 management requirements that apply to California licensed
17 pharmacies.

18 SEC. 2. The sum of three million dollars (\$3,000,000) is
19 hereby appropriated from the State Treasury to the State
20 Department of Health Services, to fund staff and contract costs
21 for the California Rx Program established pursuant to Division
22 113 (commencing with Section 130600) of the Health and Safety
23 Code.